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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,303	10/03/2003	Helene Strick-Marchand	242258US	9631

22850 7590 01/03/2007  
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/677,303

Applicant(s)

STRICK-MARCHAND ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 12-21, 24-35 and 38-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-11, 22, 23, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/02/2006</u> | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Claims 1-4, 8-11, 22, 23, 36 and 37 as amended (10/02/2006) are under examination in the instant office action.

This application contains claims 5-7, 12-21, 24-35 and 38-46 drawn to invention(s) nonelected with traverse in the papers filed on 12/19/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Deposit***

The deposit requirement has been met in the reply filed 10/02/2206.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-4, 8-11, 22, 23, 36 and 37 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 36 and 37 as amended recite two terms that are “non-transformed” cell and cell “not containing a transgene”. The particular definitions that would distinguish the specific meaning of each claimed term or the scope of each claimed term are missing in the as-field specification. Both terms appear to be equivalents since they encompass the exclusion of “foreign” DNA or presence of DNA inserted by genetic engineering techniques from one organism to another. For example: see specification at page 3, lines 24-25; page 8, line 16 page 9, lines 11-15.

Claim 37 is also indefinite because it depends on non-elected claim(s) and because it is unclear what cellular characteristics are intended for the product as claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-11, 22, 23, 36 and 37 as amended remain rejected under 35 U.S.C. 102(a) as being anticipated by Strick-Marchand et al. (Hepatology. October 4, 2002. Vol. 36, NO. 4, pages 794-804) as explained in the prior office action.

Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line. Some claims are further drawn to the cells being undifferentiated cells or stem cells or bipotential cells. Some claims are further drawn to the mammalian mouse cells or mammalian embryonic liver cells. Some claims are further drawn to the cells obtained by culturing 2-3 mounts. Some claims are further drawn to the cells being cell lines BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

The reference by Strick-Marchand et al. discloses immortalized non-transformed mammalian hepatic cell lines that are undifferentiated bipotential cells derived from mouse embryonic liver cells including cell lines BMEL-14B3 and BMEL-9A1 (table 3). The cells were cultured for at 2-3 mounts (table 1). The cited reference anticipates the claimed invention.

Claims 1, 9-10, 36 and 37 as presently amended are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,393,133 (Knowles et al.).

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Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line not containing a transgene that is obtained by culturing cells from mammalian liver. Some claims are further drawn to the cells being or capable to sustain culturing for 2-3 mounts.

US 4,393,133 (Knowles et al.) disclose a hepatic cell line Hep G2 that is isolated from human hepatoma. The cell line Hep G2 does not contain a "foreign" material or a "transgene" and, thus, it is non-transformed and/or immortalized without being transformed with a foreign gene within the meaning of the claims and in the light of specification. The cell line Hep G has been cultured at least since 1983 and, thus, for "at least for 2-3 months". Therefore, the cited cell line Hep G2 is a cultured immortalized non-transformed mammalian hepatic cell line not containing a transgene as required by the claimed invention. The cited reference anticipates the claimed invention.

Claims 1-4, 8-11, 36 and 37 as presently amended are rejected under 35 U.S.C. 102(b) as being anticipated by ATCC Catalogue 1994.

Claims are directed to a cultured immortalized non-transformed mammalian hepatic cell line not containing a transgene that is obtained by culturing cells from mammalian liver. Some claims are further drawn to the cells being or capable to sustain culturing for 2-3 mounts. Some claims are further drawn to the cells being undifferentiated cells or stem cells or bipotential cells. Some claims are further drawn to the mammalian mouse cells or mammalian embryonic liver cells.

The ATCC Catalogue (see page 330) discloses a normal mouse embryonic liver cell line BNL CL.2 (ATCC TIB-73). The cited cell line is a cultured immortalized non-transformed

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mammalian hepatic cell line that does not containing a transgene and that is undifferentiated or stem or bipotential cell line as required by the claimed invention. The cited reference anticipates the claimed invention.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-11, 22, 23, 36 and 37 as presently amended are rejected under 35 U.S.C. 102(b) as anticipated by ATCC Catalogue 1994 or, in the alternative, under 35 U.S.C. 103(a) as obvious over ATCC Catalogue 1994.

Claims 1-4, 8-11, 36 and 37 as above. Some claims are further drawn to the cells being cell lines BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

The cited reference is relied upon as explained above. The cited reference is silent about particular cell lines identified by designation numbers BMEL-14B3 (CNCM I-3100) and BMEL-9A1 (CNCM I-3099).

Thus, referenced hepatic cells appear to be identical to the presently claimed cell lines and are considered to anticipate the claimed cell lines since they are disclosed as being cultured immortalized non-transformed mammalian bipotential hepatic cells.

In the alternative, even if the claimed cell lines are not identical to the referenced cells with regard to some unidentified characteristics, the differences between that which is disclosed

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and that which is claimed are considered to be so slight that the referenced cells are likely inherently possess the same characteristics of the claimed cells particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed cell lines would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants' arguments filed 10/02/2006 have been fully considered but they are not persuasive.

1. With regard to the claim rejection under 35 U.S.C. 102(a) as being anticipated by Strick-Marchand et al. (Hepatology. October 4, 2002. Vol. 36, NO. 4, pages 794-804) applicants presented an evidence that the cited reference has been available on October 4, 2002 and a declaration stating that 2 inventors out of 4 inventors of the instant application were authors of the cited publication. Thus, the reference still remains a prior art within the meaning of 35 U.S.C. 102(a) since it is a reference by "others" or by another inventive entity. It is also noted that the contents of the declaration are rather confusing and they might raise some issues as to who is responsible for the conception and reduction to practice of the instant invention as claimed.

2. Claim rejection(s) under 35 U.S.C. 102(b) and under 35 U.S.C. 102/103 as based on the disclosure by Spagnoli et al. (The Journal of cell Biology. November 1998. Vol. 143, No. 4, pages 1101-1112) has been withdrawn because the cited hepatic cell lines are derived from

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transgenic mice that contain a human gene and, thus, the cell lines contain a transgene. The claimed cell line does not contain a transgene or foreign DNA as claimed and in the light of specification (page 8, lines 16; page 9, lines 11-16).

Applicant's arguments with respect to claims as presently amended and now drawn to "cell line not containing a transgene" have been considered but are moot in view of the new ground(s) of rejection.

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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December 22, 2006

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER